MAY 0 6 2002

February 4, 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Pre-Loaded BioStinger Hornet™.
510(k) Number K020377.

A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

Laura D. Seneff, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: Pre-Loaded BioStinger Hornet™

Common Name: Meniscal Repair Device

Classification Names: Fastener, Fixation, Biodegradable, soft tissue

Proposed Class/Device: Class II, ~~MAF~~ HWC & MAI
Product Code

D. Predicate/Legally Marketed Devices

BioStinger-V™ K991715
Linvatec Corporation

E. Device Description

The BioStinger™ Bioabsorbable Meniscal Repair Device is a cannulated, sterile, single-use fixation device made from an absorbable homopolymer derived from Poly (L-lactic) Acid, and will gradually be absorbed into the body. The implant is colored with D&C Violet #2. The implant is preloaded on a single-patient use, sterile, disposable, re-loadable inserter. The implant is radiotranslucent with regard to intraoperative fluoroscopy, but it can be visualized with MRI and CAT scan.

F. Intended Use

The BioStinger™ Bioabsorbable Implant provides fixation of longitudinal vertical meniscus lesions (bucket handle tears) located in the vascular area of the meniscus.

G. Substantial Equivalence

The Pre-Loaded BioStinger Hornet™ is substantially equivalent in design, technology and intended use to Linvatec's existing BioStinger-V™ implant. Performance testing has been conducted to show that pre-loading the implant does not raise any new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Ms. Laura D. Seneff, RAC
Manager, Regulatory Affairs
Linvatec Corp.
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K020377
Trade/Device Name: Pre-Loaded BioStinger Hornet™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastner
Regulatory Class: Class II
Product Code: HWC
Dated: February 4, 2002
Received: February 5, 2002

Dear Ms. Seneff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

February 4, 2002

510(k) Number (if known): K020377

Device Name: Pre-Loaded BioStinger Hornet™

Indications for Use:

The BioStinger™ Bioabsorbable Implant provides fixation of longitudinal vertical meniscus lesions (bucket handle tears) located in the vascular area of the meniscus.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020377